K021990

JUL 18 2002

510(k) Summary of Safety and Effectiveness
for Galt Medical's Vascular Guidewires (Mandrel Type)
(Prepared in accordance with 21 CFRPart 807.92)
Date 6/14/02

(1) **Submitter**: Galt Medical Corp.
2475 Merritt Drive
Garland, TX 75041
(972) 271-5177
Contact Person: David Catlin

(2) **Device Name:** Guidewire
Trade Name: No proprietary name has been established.
Classification Name: Wire, Guide, Catheter
Classification Code: DQX

(3) **Substantial Equivalency:** Galt Medical Corp. guidewires (Mandrel Type) are substantially equivalent to guidewires from K982559.

(4) **Device Description:** The materials of construction stainless steel, nitinol, platinum are consistent with guidewires presently in commercial distribution. The wires are available straight, or with "J" end. The wires range from .014" diameter through .025" diameter and lengths from 20cm. to 360 cm. The wires may also be PTFE coated.

These guidewires are intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature.

(5) **Technological Characteristics:** Galt Medical's guidewires have the same indications for use and are otherwise technically the same as the predicate devices.

(6) **Non-Clinical Tests:** The results of these tests demonstrated that the functionality and performance characteristics of the guidewires are comparable to the currently marketed guidewires. Tests performed include: tensile strength and torqueability.

(7) **Conclusions:** Based on the information presented in this 510(k) premarket notification, Galt Medical's guidewires are considered substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2002

Galt Medical Corporation
c/o Mr. David Catlin
Executive Vice President
2475 Merritt Drive
Garland, TX 75041-6146

Re: K021990
Guidewire
Regulation Number: 870.1330
Regulation Name: Catheter guide wire.
Regulatory Class: Class II (two)
Product Code: 70 DQX
Dated: June 14, 2002
Received: June 18, 2002

Dear Mr. Catlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

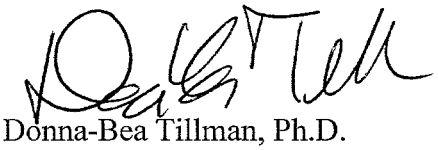
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K021990

Device Name: Vascular Guidewire (Mandrel Type)

Indications For Use: These guidewires are intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021990